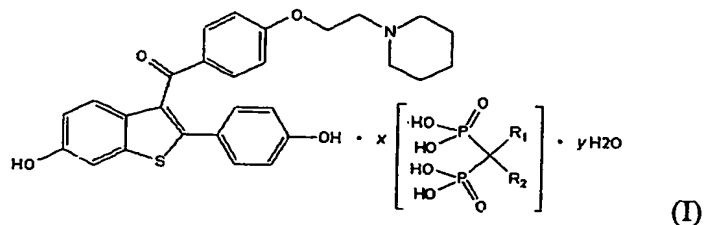


WHAT IS CLAIMED IS:

1. A mutual salt of raloxifene and bisphosphonic acid of formula (I):



wherein:

R_1 is C_{1-6} alkyl optionally substituted with one or more substituents selected from the group consisting of NR_3R_4 , OH, halogen, C_{1-6} alkylthio, phenyl, C_{3-7} cycloalkyl optionally substituted with NR_3R_4 or OH, imidazolyl, pyridyl and imidazopyridyl; C_{3-6} cycloalkyl optionally substituted with one or more substituents selected from the group consisting of NR_3R_4 , OH, halogen, C_{1-6} alkylthio, phenyl, morpholine and pyridyl; NR_3R_4 ; halogen; C_{1-6} alkylthio optionally substituted with one or more substituents selected from the group consisting of NR_3R_4 , OH, halogen and phenyl; or phenylthio optionally substituted with one or more substituents selected from the group consisting of halogen, nitro, C_{1-6} alkyl, C_{1-6} alkoxy, trifluoromethyl, $CONR_3R_4$ and CO_2H ;

R_2 is hydrogen, OH or halogen;

R_3 and R_4 are each independently hydrogen, C_{1-6} alkyl or C_{3-6} cycloalkyl, wherein R_3 and R_4 are optionally fused together with the nitrogen atom to which they are attached to form a 5 to 7-membered ring;

x is 0.5 or 1; and

y is an integer in the range of 0 to 10.

2. The mutual salt of claim 1, wherein R_1 is C_{1-6} alkyl optionally substituted with one or more substituents selected from the group consisting of NR_3R_4 , imidazolyl and pyridyl;

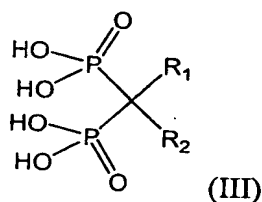
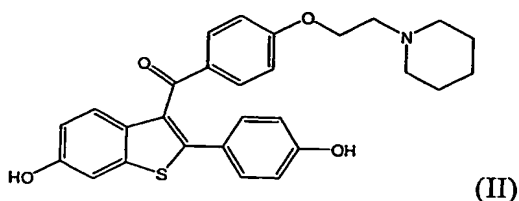
NR_3R_4 ; halogen; or phenylthio substituted with halogen, and y is an integer of 0 to 7.

3. The mutual salt of claim 1, wherein the bisphosphonic acid part is selected from the group consisting of 1-hydroxyethylidene bisphosphonic acid (etidronic acid),
5 dichloromethylidene bisphosphonic acid (clodronic acid), 3-amino-1-hydroxypropylidene bisphosphonic acid (pamidronic acid), 4-amino-1-hydroxybutylidene bisphosphonic acid (alendronic acid), 4-chlorophenylthiomethylidene bisphosphonic acid (tiludronic acid), 3-(N-methyl-N-n-pentyl)amino-1-hydroxypropylidene bisphosphonic acid (ibandronic acid),
1-hydroxy-2-(3-pyridinyl)ethylidene bisphosphonic acid (risedronic acid),
10 cycloheptylaminomethylidene bisphosphonic acid (incadronic acid),
1-hydroxy-2-(1-imidazolyl)ethylidene bisphosphonic acid (zoledronic acid) and
1-hydroxy-3-(pyrrolidinyl)propylidene bisphosphonic acid.
4. The mutual salt of claim 1, which is raloxifene 1/2etidronate 5/2hydrate, raloxifene
15 pamidronate trihydrate, raloxifene alendronate pentahydrate, raloxifene risedronate trihydrate, raloxifene incadronate monohydrate, or raloxifene zoledronate tetrahydrate.
5. The mutual salt of claim 1, which is raloxifene alendronate pentahydrate.
- 20 6. The mutual salt of claim 5, whose powder X-ray diffraction spectrum ($I/I_0 \geq 20$) shows at 2θ values of 4.2 ± 0.2 , 8.4 ± 0.2 , 9.4 ± 0.2 , 9.7 ± 0.2 , 10.8 ± 0.2 , 13.3 ± 0.2 , 13.8 ± 0.2 , 14.2 ± 0.2 , 16.7 ± 0.2 , 18.3 ± 0.2 , 18.6 ± 0.2 , 19.4 ± 0.2 , 19.8 ± 0.2 , 20.5 ± 0.2 , 20.8 ± 0.2 , 21.2 ± 0.2 , 21.6 ± 0.2 , 25.5 ± 0.2 and 26.9 ± 0.2 .
- 25 7. The mutual salt of claim 1, which is raloxifene risedronate trihydrate.
8. The mutual salt of claim 7, whose powder X-ray diffraction spectrum ($I/I_0 \geq 20$) shows at 2θ values of 6.8 ± 0.2 , 10.3 ± 0.2 , 12.3 ± 0.2 , 15.2 ± 0.2 , 16.5 ± 0.2 , 17.0 ± 0.2 , 17.3 ± 0.2 ,

19

17.7±0.2, 20.3±0.2, 20.9±0.2, 21.2±0.2, 19.4±0.2, 19.8±0.2, 20.5±0.2, 20.8±0.2, 21.2±0.2, 21.6±0.2, 25.5±0.2 and 26.9±0.2.

9. A process for preparing a mutual salt of raloxifene and bisphosphonic acid of formula (I),
 5. which comprises the step of reacting a compound of formula (II) or its solvate with a compound of formula (III) or its solvate, in a solvent:

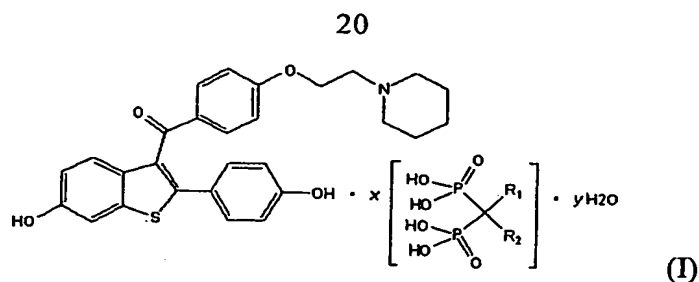


- 10 wherein R₁ and R₂ have the same meanings as defined in claim 1.

10. The process of claim 9, wherein the solvent is selected from the group consisting of water, methanol, ethanol, propanol, isopropanol, acetone, tetrahydrofuran, 1,4-dioxane, acetonitrile, N,N-dimethylformamide, and a mixture thereof.

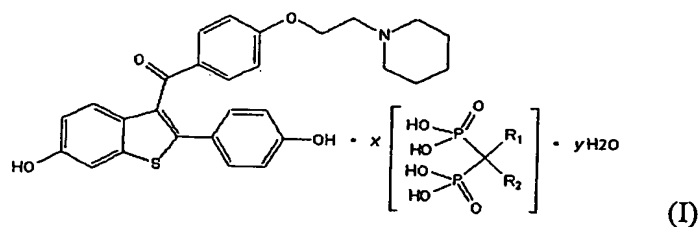
15

11. A pharmaceutical composition for preventing and treating osteoporosis comprising the mutual salt of formula (I) as an active ingredient together with pharmaceutically acceptable carriers:



wherein R_1 , R_2 , R_3 , R_4 , x and y have the same meanings as defined in claim 1.

- 5 12. A pharmaceutical composition for preventing and treating hypercalcemia comprising the mutual salt of formula (I) as an active ingredient together with pharmaceutically acceptable carriers:

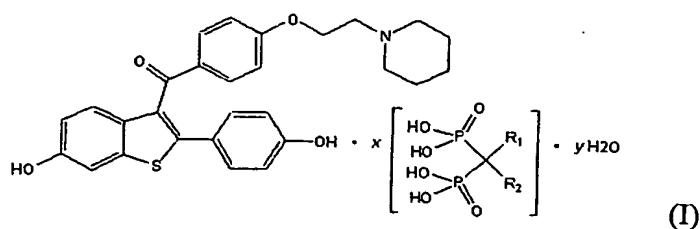


10

wherein R_1 , R_2 , R_3 , R_4 , x and y have the same meanings as defined in claim 1.

13. A pharmaceutical composition for preventing and treating hyperlipidemia comprising the mutual salt of formula (I) as an active ingredient together with pharmaceutically acceptable carriers:

15



wherein R_1 , R_2 , R_3 , R_4 , x and y have the same meanings as defined in claim 1.